K071473

510(k) Summary

JUL 12 2007

superDimension Ltd.
Special 510(k)
Changes to superDimension/Bronchus Premium 2

Date Prepared:

05/25/2007

510(k) Applicant:

superDimension Ltd.
8 Hamenofim St., P.O. Box 2045
Herzliya 46120
Israel
Ph: +972-(0)9-971-3700
Fax: +972-(0)9-971-3701

510(k) Application Correspondent:

Clay Anselmo
President and COO
Reglera
555 Zang St., Suite 100
Lakewood, CO 80228
Ph: 303-223-4303
Cell: 303-907-2955
Fax: 303-832-6700
Email: anselmoc@reglera.com

Name of Device:

Trade name:	superDimension/Bronchus Premium 2
Common name:	Bronchoscope
Classification name:	Computed tomography x-ray system 21 CFR 892.1750 Product code JAK

Equivalent Legally-Marketed Device:

superDimension/Bronchus Premium 2, K062315

Description:

The superDimension/Bronchus Premium 2 is a device that guides a bronchoscope and bronchial tool to a target in or adjacent to the bronchial tree on a path indicated by CT scan, and visualizes the target and the interior of the tree.

Intended Use:

The superDimension/Bronchus Premium 2 is indicated for displaying images of the tracheobronchial tree to aid the physician in guiding endoscopic tools in the pulmonary tract. It does not make a diagnosis and is not an endoscopic tool. It is not for pediatric use.

Summary of Characteristics Compared to Predicate Device:

Changes are being made to the superDimension/Bronchus Premium 2 to include modifications to some of its disposable components and changes to portions of its labeling.

The intended use and indications for use of the modified device, as described in its labeling, are the same as the intended use and indications for use of the 510(k) Applicant's unmodified predicate device.

The modified device has the same technological characteristics as the unmodified predicate device.

Performance Data:

The changes being made to the superDimension/Bronchus Premium 2 were subjected to superDimension's design control process. A risk analysis was performed to analyze the hazards associated with the changes. Appropriate verification and validation tests were performed to assure that the design output met the design input requirements and that the modified device continues to meet its user needs and intended uses.

Clinical Data:

Clinical tests were not required to validate the changes made to the superDimension/Bronchus Premium 2.

Conclusion:

The superDimension/Bronchus Premium 2 is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

SuperDimension Ltd.
% Mr. Clay Anselmo
President and CEO
Reglera
555 Zang Street, Suite 100
LAKEWOOD CO 80228

JUL 12 2007

Re: K071473
Trade/Device Name: superDimension/Bronchus Premium 2
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulation Numer: 21 CFR 874.4680
Regulation Name: Bronchoscope (flexible or rigid) and accessories
Regulatory Class: II
Product Code: JAK and EOQ
Dated: May 25, 2007
Received: May 29, 2007

Dear Mr. Anselmo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071473

Device Name: superDimension/Bronchus Premium 2

Indications for Use:

Indicated for displaying images of the tracheobronchial tree to aid the physician in guiding endoscopic tools in the pulmonary tract. It does not make a diagnosis and is not an endoscopic tool.

Not for pediatric use.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K071473